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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,515	12/18/2001	William E. Weblar	ACS-60271 (2168P)	6307

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EXAMINER

LEUBECKER, JOHN P

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 08/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/025,515

Applicant(s)

WEBLER ET AL

Examiner

John P. Leubecker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 and 22-34 is/are pending in the application.
- 4a) Of the above claim(s) 10-16, 18 and 22-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 17, 19, 31-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Specification

1. The abstract of the disclosure is objected to because for the reasons set forth in numbered paragraph 2 of the previous Office Action. Correction is required. See MPEP § 608.01(b).

2. The disclosure is objected to because of the following informalities: serial numbers indicated as “XXX” and “YYY” on page 19 need to be replaced with the actual serial numbers.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 6 and 7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 6 and 7 now recite that the outer diameter of the ferrule is “less than about 0.01 inch” and “less than about 0.006 inch” (claim 1 recites plural diameters and claims 6 and 7 refer back to such). *The smaller dimensions are comparable to the diameter of a human hair.* Although the specification mentions these diameters in a non-specific manner (i.e., does not specify whether these dimensions are referring to inner or outer diameters), it was assumed that

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the inner diameters were intended, since such would be reasonable with respect to accommodating the typical diameter of an optical fiber. It is not clear how a ferrule could be manufactured with an outer diameter of less than 0.01 inch to include an aperture for accommodating an optical fiber and an outer diameter with a tolerance to provide a “friction fit” with a sheath, such sheath being typically much greater in diameter and manipulated by the hand for insertion into the body.

Claim Rejections - 35 USC § 102

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1-5, 8, 9, 17, 19 and 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Forkner et al. (U.S. Pat. 4,750,476).

Forkner et al. disclose an elongated shaft (17,19), the proximal portion (proximal portion of 19) having a substantially constant outer diameter (Fig.1), an optical pathway (space within distal end of the shaft 17), an internal surface (inner surface of shaft 17) defining a internal chamber (space within proximal end of shaft 17), an elongated optical fiber (41), and a ferrule (21) attached to the optical fiber and having an constant diameter outer surface (surface shown in Fig.1 containing fitting 55) that is substantially the same as the outer diameter of the proximal portion of the shaft (17) (note Fig.1). Thread (not numbered but shown in Fig.1) between the proximal portion of the shaft (17) and the distal portion of the ferrule (21) allows a secured

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position and a released position, wherein, in the released position, the shaft (17) will inherent be able to rotate "freely".

As to claim 2, a threaded connection considered to be a part friction-fit connection. As to claim 3, note that the threads exist between a portion of the ferrule outer surface and a portion of the shaft inner surface (Fig.1). As to claim 4, the shaft/optical fiber of Forkner et al. can be considered an optical guidewire. As to claim 5, the ferrule distal outer surface is cylindrical and rounded (Fig.1). As to claims 8 and 9, the ferrule proximal portion is configured to form an operable optical and mechanical connection with the eyepiece optics (not numbered but inherently in the eyepiece housing) and the eyepiece housing (15), respectively (Fig.1). As to claim 17, the structure of the optical guide wire is described above. The optical and mechanical connection of the ferrule (21) to the eyepiece housing (15) forms optical and mechanical connectors. Since the eyepiece housing is inherently rotatable in space, the mechanical connector will be rotatable and the ferrule will rotate "when engaged to said mechanical connector while said mechanical connector rotates". As seen in Figure 1, the ferrule distal portion is configured to be disposed within the shaft internal chamber (claims 31 and 33). As to claims 32 and 34, the proximal aperture (roughly where lead line 17 points) of the ferrule can be considered a "slot".

7. Claims 1-5, 8, 9, 17, 19 and 31-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Oneda et al (U.S. Pat. 4,979,498).

Oneda et al. disclose an elongated shaft (4,12), the proximal portion (the proximal portion of 12) having a substantially constant outer surface (Fig.1), an optical pathway (space within the

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distal end of shaft 4), an internal surface (inner surface of shaft 4) defining an internal chamber (space within proximal end of the shaft 4), an elongated optical fiber (labeled as 17 but is described as extending through cable 14 to light guide 3) disposed at least in part within said internal chamber of the shaft (distal end of the optical fiber at 3 will be within internal chamber when the shaft is connected to the ferrule--note that fitting 12A will be within slot of fitting 12, making the distal end of the optical fiber 3 within the internal chamber), and a ferrule (cylindrical housing structure of the device proximate to 12A and 3) wherein the proximal portion (section between 12A and 2 with a constant outer diameter) has an outer diameter that is substantially the same as the outer diameter of the shaft proximal portion (12) (note Fig. 1). When fitting 12 is connected to 12A, the ferrule is secured to the shaft and when released, each are inherently free to rotate with respect to each other.

As to claims 2 and 3, the connection of the fitting 12A on the outer surface of the ferrule in recess on the interior surface of fitting 12 will provide a friction fit. As to claim 4, optical instrument of Oneda et al. can be considered an optical guidewire. As to claim 5, the distal outer surface of the ferrule (portion shown distally of 3) is cylindrical and round. As to claim 8, the ferrule is operably optically (optical fiber) and mechanically connected to focus ring (2) and handle (13). As to claim 17, the optical and mechanical connectors the connection of optical and mechanical connection of light guide (3) with transparent sleeve (4) or the optical (though the optical fiber extending proximally) and mechanical connection of the proximal end of the ferrule (noted above as the portion between 12A and 2 in Figure 1) with focus ring 2 or handle (13). As to claims 31 and 33, the ferrule distal portion is disposed within the internal chamber when the

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shaft is connected to the ferrule. As to claims 32 and 34, the recess in fitting (12, Fig. 1) which connects with protrusion (12A) defines a slot in the proximal portion of the shaft.

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Forkner et al. in view of Swanson et al. (U.S. Pat. 5,445,939) and separately in view of Oneda et al. in view of Swanson et al.

Forkner et al. disclose a ferrule diameter of greater than 0.02 inch (note that the image guide itself is 0.5 mm) and Oneda et al. disclose an optical fiber through the ferrule (which would include a diameter) but fails to disclose such diameter. Notwithstanding the fact that a change in size is not usually considered a patentable invention (A change in the size of a prior art device is a design consideration within the skill of the art. In re Rose, 220 F.2d 459, 105 USPQ 237 (CCPA 1955)) where miniaturization is considered desirable in this art, Swanson et al. discloses that an imaging optical fiber (which would evidence that one this small can transmit illumination light as well) can be on the order on 0.005 inches (col.4, lines 16-47). It would have been obvious to use the smallest known diameters of optical components in each of the Forkner et al. and Oneda et al. devices in order to make the devices smaller—a desirable feature in this art for allowing access to extremely small locations in the body.

Response to Arguments

10. Applicant's arguments filed May 23, 2005 have been fully considered but they are not persuasive.

Applicant arguments are based on the claims as amended. The amended claims have been addressed above. It is noted that other cited prior art references also show a constant diameter between the proximal end of the shaft and the proximal end of the ferrule (e.g., note diameters of elements 12 and 25 of Nakajima et al.). It is noted that the Examiner has not and is not required to apply every prior art reference to the claims. Instead the best prior art reference(s) is selected which sets forth the Examiner's position with respect to the claims as they appear. It is suggested that Applicant attempt to overcome all prior art of record, not just the references selected to be used in a rejection.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

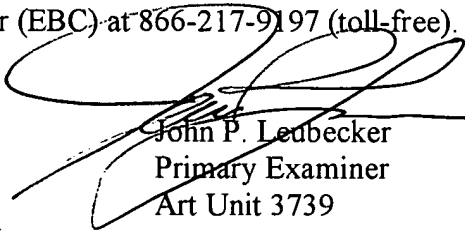
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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Leubecker whose telephone number is (571) 272-4769. The examiner can normally be reached on Monday through Friday, 6:00 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John P. Leubecker
Primary Examiner
Art Unit 3739

jpl